

**CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED
PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)**

**MODÜL C2 - ÜRETİMİN DÂHİLÎ KONTROLÜ VE ÜRÜNÜN RASTGELE
ARALIKLARLA DENETİMLİ MUAYENESİNE DAYALI TİPE UYGUNLUK**

Belge No / Certificate No : 90-20-01-01
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 22.04.2021-22.04.2022
Belge Geçerlilik Tarihi / Document Validity Period : 1 yıl / 1 year
**Firma Unvanı ve Adresi /
Company Name and Address** : OLEY TIBBİ ÜRÜNLER VE MEDİKAL MALZEMELER
SAN. TİC. LTD. ŞTİ.
Parseller Mah. Menekşe Cad. Feyyaz Sok. No: 2 Ümraniye/
İSTANBUL/ TÜRKİYE
Ürün Adı /Modeller / Product Name / Models : OLEY 2311
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : C2 MODÜLÜ/ KATEGORİ III
MODULE C2 / CATEGORY III
Test Rapor No/ları / Test Report No : MNA M-2021-00554
Ürün Tipi / Product Type:
- EN ISO 13688 Koruyucu giyecekler - Genel özellikler / *Protective clothing - General requirements*
- EN 13034+ A1 Sıvı Kimyasallara Karşı Koruyucu Giysi (Tip 6-B) / *Protective Clothing Against Liquid
Chemicals (Type 6-B)*
- EN ISO 13982-1 Katı Parçacıklara Karşı Koruyucu Giysi (Tip 5-B)/ *Protective Clothing For Use Against Solid
Particulates (Type 5-B)*
- EN 14605+A1 Koruyucu Giyecekler - Sıvı Kimyasal Maddelere Karşı (Tip 3-B, Tip 4-B) / *Protective clothing
against liquid chemicals (Type 3-B, Type 4-B)*
- EN 14126 Koruyucu Giyecekler - Patojen Organizmalara Karşı / *Protective Clothing - Performance
Requirements And Tests Methods For Protective Clothing Against Infective Agents*
Ürünün Malzeme Bilgisi / Product Material Information: OLEY 2311 model ürünleri kaplamalı kumaş kullanılarak
imal edilmiştir./ OLEY 2311 model products are manufactured using coated fabric.

Volkan AKIN
22.04.2021
Karar Verici / Approver



Okan AKEL
22.04.2021
Şirket Müdürü / General manager



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(MODULE C2, ANNEX VII) (90-20-01-01)**

Report No : 90-20-01-01

Report Date : 22.04.2021

Application No : 90-20-01

1. COMPANY INFORMATION:

OLEY TIBBİ ÜRÜNLER VE MEDİKAL MALZEMELER SAN. TİC. LTD. ŞTİ.
Parseller Mah. Menekşe Cad. Feyyaz Sok. No: 2 Ümraniye/ İSTANBUL/ TÜRKİYE
Tel: 0 216 611 93 33
Fax: 0 216 611 93 22

2. PPE INFORMATION:

Disposable non-sterile coverall.

3. PPE TYPE IDENTIFICATION

EN 13688 Protective clothing - General requirements
EN 13034 Protective clothing against liquid chemicals (Type 6-B)
EN ISO 13982-1 Protective clothing for use against solid particulates (Type 5-B)
EN 14605+ A1 Protective clothing against liquid chemicals (Type 3-B, 4-B)
EN 14126 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

4. PPE PICTURES



5. PPE DIMENSIONS:

OLEY 2311 model product has been found to be produced using S-M-L-XL-2XL size.

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6. PPE PRODUCT MATERIAL INFORMATION:

- The product is made of coated fabric.

7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- Protective clothing doesn't contain any sharp or hard edges or rough surfaces.
- Wearer donned and removed without any difficulties and clothing fits perfectly.
- The clothing doesn't obstruct blood circulation in any part of the body.
- The clothing design at armholes and crotch are appropriately proportioned and positioned.
- Sufficient closure arrangements given in the clothing and all the closures systems functioning properly.
- The coverage of protection zones of protective material is maintained during movements as extreme as it is anticipated a user would make.
- Wearer doesn't observe any difficulties while standing, sitting, walking, stair climbing, raising both hands above the head and bending over and picking up a small objects.
- While movements the protective material covers body area sufficiently.
- No difficulties in putting on and removing other items of PPE such as gloves and boots.

8. ANALYSIS AND EVALUATIONS:
EN ISO 13688

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
pH value	6,82	3,5 – 9,5	PASS

EN 13034

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance	>10 cycles	1	PASS
Tear resistance	33,41 N	2	PASS
Tensile strength	35,17 N	1	PASS
Puncture resistance	5,66 N	1	PASS
Repellency to liquids	H2SO4: 99,3 NaOH: 99,5	3 3	PASS
Resistance to penetration by liquids	H2SO4: 0,8 NaOH: 0,7	3 3	PASS
Resistance to penetration by spray liquid (spray test)	0 cm ²	-	PASS
Seam Strength	50,41 N	2	PASS

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EN ISO 13982-1

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Total inward leakage	Ljmn82/90: 16,3 Ls8/10: 13,9 (%)	IL 82/90 <30% and TILS 8/10<15%	PASS
Flex Cracking resistance	500 cycles	1	PASS

EN 14605+A1

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to penetration by jet liquid (jet test)	0cm ²	-	PASS
Permeation	No leakage (%40 NaOH 30 min)	2	PASS

EN 14126

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Penetration by blood borne pathogens (Bacteriophage)	3,5 kPa 0 (PFU/ml)	3	PASS
Resistance to wet bacterial penetration	%0,15	1	PASS
Resistance to penetration by biologically contaminant dust	2,03 (log cfu)	1	PASS

9. DECISION PROPOSAL

Analysis and examinations OLEY 2311 model coded personal protective equipment; EN 13688, EN 14605+A1, EN 14126, EN ISO 13982-1, EN 13034 are evaluated. The homogeneity of the production was monitored at the performance levels determined as a result of the technical evaluations made within the scope of MODULE C2.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports (M-2021-00554)
- User Instruction

CONTROLLER : VOLKAN AKIN

SING :

DATE : 22.04.2021

